REMARKS

Upon entry of this amendment, claims 1, 2, 4-19, 21-24, 51, 52 and 53 are pending in the application. Claim 3 has been canceled herein. Claims 1, 13, 14, 22, 23, 24, and 51 have been amended. Support for the amendments can be found at least at page 6, lines 15-27 and page 21, lines 5-6 of the specification. New claims 52 and 53 have been added. Support for new claims 52 and 53 can be found at least at page 28, lines 12 through 25. No new matter has been added.

Objections to the Specification

The specification is objected to as failing to provide proper antecedent basis for claim 14, which recites a polymer having a chain length of from about 4 to 100 sugar units. (*See* Office Action at page 2.) According to the Examiner, claims to gluco-oligosaccharides (GOS), raffinose-based oligosaccharides, and other long-chain oligosaccharides are not supported by the originally-filed specification. Applicants disagree.

Support for pending claim 14 can be found at least in original claim 14 and at page 17, lines 5-6. Support for pending claim 13 can be found at least in original claim 13 and at page 16, lines 6-8. This rejection should be withdrawn.

Objections to the Claims

Claims 1, 3, 23, and 24 are objected to because the proper taxonomic classification of organisms according to genus-species should be italicized. Claim 3 is objected to because of a typographical error in "*L. sporogenes*". Claim 14 has been objected to because the claim language is awkward. (*See* Office Action at page 3.)

Claim 3 has been canceled herein. Thus, the rejection, as it applies to this claim, is moot and should be withdrawn. The remaining claims have been amended to address each of the Examiner's concerns. This rejection should be withdrawn.

35 USC § 112, first paragraph, enablement

Claims 1-19, 20-24, and 51 are rejected under 35 U.S.C. § 112, first paragraph for not being enabled for preventing bacterial gastrointestinal infection. (*See* Office Action at page 3.) Claim 1, from which the remaining claims depend, directly or indirectly, has been amended to

recite a method of reducing a bacterial gastrointestinal infection by orally administering *Bacillus coagulans* to a human, which the Examiner indicates is enabled. This rejection should be withdrawn.

35 USC § 112, second paragraph, indefiniteness

Claims 3 and 22 are rejected under 35 U.S.C. 112, second paragraph for being indefinite. (*See* Office Action at page 6.) Claim 3 has been canceled herein. Thus, the rejection, as it applies to this claim, is moot and should be withdrawn. The Examiner states that the phrase "20-25 glucose" is missing the proper unit of measure. The Examiner further contends that claims 13 and 14 lack clear antecedent basis. (*See* Office Action at page 6.)

The claims have been amended to insert the appropriate unit of measure. This rejection should be withdrawn.

Rejection under 35 U.S.C. §102

Claims 1, 2, 5, 7, 9 and 11 are rejected under 35 U.S.C. §102(b) as being anticipated by WO 91/15199 ("Shacknai"). According to the Examiner, Shacknai describes the administration of an oral electrolyte formulation comprising a non-pathogenic bacteria (but not *Bacillus coagulans*) to treat diarrhea caused by bacterial infection. (*See* Office Action at page 7.)

As stated above, claim 1, from which the remaining claims depend, directly or indirectly, has been amended to recite a method of reducing a bacterial gastrointestinal infection by orally administering *Bacillus coagulans* to a human. Shacknai fails to describe or suggest the administration of *Bacillus coagulans* to treat gastrointestinal infection. Applicants submit that Shacknai does not anticipate the claimed invention. This rejection should be withdrawn.

Rejection under 35 U.S.C. §103

Claims 1 and 12-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 5,968,569 ("Cavadini") in view of Shacknai. (*See* Office Action at page 8.) According to the Examiner, Cavadini describes the preparation of food products that contain probiotic microorganisms including *B. coagulans* for use in the treatment and inhibition of intestinal pathogens in humans. The Examiner states, "Cavadini further teaches the oral electrolyte formulation, 'Bio NAN'". (Office Action at page 9.) The Examiner additionally

states that the composition of the oral electrolyte maintenance formulation lacks functional language in the disclosure. (*See* Office Action at page 11.)

Contrary to the Examiner's contention, the teachings of the specification clarify the composition of the oral electrolyte maintenance formulation.

> An oral electrolyte maintenance powder is formulated to contain sodium chloride, potassium citrate, citric acid, glucose and powdered *B. coagulans* spores (prepared substantially as described in Example 2) to be rehydrated with sterile or boiled (and cooled) water. After rehydration, the final concentrations are: 45 to 75 mEq/l of sodium, 20 mEq/l of potassium, 35 to 65 mEq/l of chloride, 30 mEq/l of citrate, 20-25 g/l of glucose and 5×10^5 to 5×10^7 spores/l. (Specification at page 28, lines 13-18.)

Moreover, one skilled in the art would have no difficulty understanding the metes and bounds of the claim terms "oral electrolyte maintenance formulation" and would have no difficulty determining whether or not a given composition was an "oral electrolyte maintenance formulation".

In addition to dehydration, an imbalance of electrolytes can lead to a variety of physiological problems: elevated potassium levels may result in cardiac arrhythmias; decreased extracellular potassium produces paralysis; excessive extracellular sodium causes fluid retention, and decreased plasma calcium and magnesium can produce muscle spasms of the extremities. As electrolyte balance is crucial to many body functions, those skilled in the art recognize that oral electrolyte solutions are intended for the mitigation of fluid and electrolyte losses and subsequent disruptions of metabolic activity. Oral electrolyte solutions, such as Gatorade™ and Pedialyte®, are intended to prevent and treat dehydration by replenishing lost fluid and electrolytes (sodium and potassium salts). As such, the active and predominant ingredients of oral electrolyte solutions, *e.g.,* Gatorade™, typically include citric acid, sodium chloride, sodium citrate, monopotassium phosphate, and other electrolytes.

Contrary to the Examiner's contention, Cavadini's BIO NAN® is a milk-based infant formula, not an oral electrolyte formulation, as required by the claims. (*See* Cavadini at column 1, paragraph 3.) Although BIO NAN® is largely made up of milk, carbohydrates and proteins, the infant formula does contain trace amounts of sodium and potassium. However, the mere presence of potassium and sodium in a composition does not qualify that composition as an oral electrolyte maintenance formulation. In fact, BIO NAN® contains 5 mg of sodium (0.1% of the total composition) and 22 mg of potassium (0.5% of the total composition) per serving. The

concentration of sodium and potassium in BIO NAN® would not be sufficient to replenish or maintain electrolyte balance in a human, and the skilled artisan would not characterize BIO NAN® as an oral electrolyte maintenance formulation.

By contrast, the claimed oral electrolyte maintenance formulation contains high concentrations of electrolytes to mitigate fluid and electrolyte losses as described in Example 5 of the specification. Specifically, new claim 53 specifies that the oral electrolyte maintenance formulation comprises 30%-35% sodium, 9% to 13% potassium, 23%-30% chloride,14%-20% citrate, and 12%-13% glucose. Applicants submit that Cavadini does not report or suggest an oral electrolyte maintenance formulation, as required by the pending claims.

Secondary references, Shacknai and Langhendries do not cure the deficiencies of Cavadini, as neither Shacknai, nor Langhendries reports or suggests a method of reducing a bacterial gastrointestinal infection by orally administering *Bacillus coagulans* in an oral electrolyte maintenance formulation to a human.

For each of the above-mentioned reasons, Applicants submit that this rejection should be withdrawn.

Double Patenting

Claims 1-11 and 19-25 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13 and 14 of US Patent Number 6,461,607, and claims 1-10 of US Patent Number 6,849,256.

In response, Applicants submit herewith terminal disclaimers in compliance with 37 C.F.R. § 1.321 (c) along with the appropriate fees. Thus, this rejection is now moot and should be withdrawn.

Claims 12-18 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13 and 14 of US Patent Number 6,461,607 and claims 1-10 of US Patent Number 6,849,256, in view of Cavadini *et al.* (US Patent Number 5,968,569).

As mentioned above, Applicants submit herewith terminal disclaimers in compliance with 37 C.F.R. § 1.321 (c) along with the appropriate fees. Thus, this rejection is moot and should be withdrawn.

CONCLUSION

On the basis of the foregoing amendments, Applicants respectfully submit that the pending claims are in condition for allowance. If there are any questions regarding these amendments and remarks, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,

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